

REMARKS

Claims 1 – 28 are currently pending in the application. Reconsideration of the rejected claims is respectfully requested in view of the following remarks.

Summary of the Office Action

In the instant Office Action, the Examiner has rejected claims 1, 3, 7, 9, 13, 15 – 19 and 24 – 28. Additionally, claims 2, 4 – 6, 8, 10 – 12, 14 and 20 – 22 were objected to. By the present remarks, Applicants submit that the rejections have been overcome, and respectfully request reconsideration of the outstanding Office Action and allowance of the present application.

Interview Summary

Applicants gratefully acknowledge the courtesy extended by Examiner Lau and Supervisory Examiner Hofsass in granting an interview on November 9, 2006. In the interview, Applicant's representatives presented arguments regarding the rejection under 35 U.S.C. §103(a), generally stating that the applied prior art does not teach or suggest all of the features of the claimed invention and that there was no proper motivation to combine the references, as set forth in more detail below. Moreover, the drawing objection was discussed, as well as suggestions by the Examiner to overcome this objection.

While an agreement was not reached, the Examiners indicated, pending further consideration, the claims appear allowable.

Allowed Claims

Applicants acknowledge the indication that claims 2, 4 – 6, 8, 10 – 12, 14, and 20 – 22 contain allowable subject matter. However, because Applicants believe all of the claims are in condition for allowance for the following reasons, the claims are not being presented in independent form at this time.

Objection to the Drawing

The Examiner objected to the drawing and asserted that the components need to be labeled instead of numbered. In accordance with the Examiner's suggestion, Applicants have submitted a Replacement Sheet including Figure 1, showing labels for the major components. Thus, Applicants submit that the drawing objection has been overcome. Accordingly, Applicants respectfully request that the drawing objection be withdrawn, and the drawings be indicated as acceptable.

35 U.S.C. § 103(a) Rejection

Claims 1, 3, 7, 9, 13, 15 – 19 and 24 – 28 were rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent Application No. 2002/0143320 issued to Levin (hereinafter LEVIN) in view of U.S. Patent No. 5,969,606 issued to Reber et al. (hereinafter REBER). These rejections are respectfully traversed.

The Examiner bears the initial burden of factually supporting any *prima facie* conclusion of obviousness. To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in

the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all of the claim limitations. MPEP § 2142. The Examiner asserts that the applied prior art teaches or suggests all of the features of the claimed invention. Applicants respectfully disagree and submit that the Examiner has failed to establish a *prima facie* case of obviousness.

Independent Claim 1

Claim 1 recites, in relevant part:

defining a maximum allowed time dT for being kept outside a controlled-atmosphere enclosure; and

allowing the blood bag to be *requalified* when it is returned to the enclosure when both the time dT and the expiration date have not expired, and for the blood bag to be *dequalified* when one of the time dT and the expiration date have expired.

With regard to claim 1, the Examiner asserts that LEVIN teaches each and every limitation of claim 1, with the exception that LEVIN fails to teach “defining a maximum allowed time dT for being kept outside a controlled-atmosphere enclosure.” The Examiner asserts that REBER teaches this feature and that it would have been obvious to combine the teaching of LEVIN with REBER. First, Applicants respectfully disagree that LEVIN teaches the features of *requalification* and *dequalification*, and *defining a maximum allowed time*. Second, it is submitted that REBER does not compensate for these deficiencies in LEVIN. Third, Applicants respectfully disagree that it would have been obvious to combine LEVIN and REBER in the manner asserted by the Examiner.

No Teaching or Suggestion of Monitoring Two Distinct Events

Neither LEVIN nor REBER teach or suggest monitoring two distinct events or triggering an alarm based on two distinct events. More specifically, neither LEVIN nor REBER teaches or suggests monitoring two distinct events and a requalification based upon the nonoccurrence of two events. Additionally, neither LEVIN nor REBER teaches or suggests a dequalification and an alarm triggering based upon the occurrence of at least one of two events. Rather, LEVIN discloses an alarm indication in the *single* event that an expiration date of blood has passed. Moreover, while REBER discloses activating an alarm when the *single* event that a product is too long outside of an enclosure, the art of record fails to provide any teaching or suggestion for providing alarms based upon two distinct conditions, as asserted by the Examiner.

As neither of the applied documents teach or suggest the above-noted feature, Applicants submit that no proper combination of LEVIN and REBER can render obvious the present invention recited in at least independent claim 1.

No Teaching or Suggestion of Maximum Allowed Time dT

Neither LEVIN nor REBER teach or suggest a maximum allowed time dT for being kept outside a controlled-atmosphere enclosure. The Examiner acknowledges that LEVIN fails to teach defining a maximum allowed time dT for being kept outside a controlled-atmosphere enclosure. The Examiner asserts, though, that REBER compensates for this deficiency. Applicants note that REBER discloses determining whether a time duration that a food item is outside of a storage place exceeds a predetermined threshold, and if so, indicating an alert. (REBER, col. 4, line 50 – col. 5,

line 41.) Specifically, REBER discloses that the time duration can be determined from the difference between when the food item was removed from and returned to a storage place. (REBER, col. 5, lines 15-40.) However, in contrast to the invention, REBER does not teach indicating an alert when a maximum allowed time dT outside the storage place exceeds the threshold. For example, by the method disclosed in REBER, a food item (such as mayonnaise) may be kept outside of a storage place (such as a refrigerator) for ten minutes each day. But, even after twenty-four days of keeping mayonnaise outside of the refrigerator for ten minutes at a time, thereby establishing a time dT of four hours outside of the refrigerator, REBER does not teach or suggest this condition warrants an alert. Thus, REBER, like LEVIN, fails to teach or suggest defining a maximum allowed time dT for an item being kept outside a controlled environment, such that no proper combination of LEVIN and REBER can render obvious the present invention recited in at least independent claim 1.

Additionally, Applicants submit that there is no teaching or suggestion in the art that blood has a useful life dT outside of a controlled enclosure, nor is there any arguable suggestion of any perishable product having such a useful life dT, as recited in the pending claims.

As neither of the applied documents teach or suggest the above-noted feature, Applicants submit that no proper combination of LEVIN and REBER can even arguably render unpatentable the present invention recited in at least independent claim 1.

For all these reasons, no proper combination of LEVIN and REBER can the combination of features recited in claim 1.

Independent Claims 9, 19, and 26

While the Examiner asserts that claims 9, 19, and 26 correspond to claim 1, Applicants submit that claims 9, 19, and 26 recite different scopes of the invention than recited in independent claim 1.

Specifically, claim 9 recites, in relevant part:

monitoring a maximum allowed time dT that a blood bag may be kept outside a controlled-atmosphere enclosure...;

indicating whether the blood bag may be transfused to a patient when both the time dT and the expiration date have not expired; and

indicating whether the blood bag may not be transfused to a patient when one of the time dT and the expiration date has expired.

And, claim 19 recites, in relevant part:

monitoring a maximum allowed time dT that a blood bag may be kept outside a controlled-atmosphere enclosure...;

indicating whether the blood bag may be transfused to a patient when the time dT and the expiration date have not expired.

Finally, claim 26 recites, in relevant part:

... defining a maximum allowed time dT that a blood bag may be kept outside a controlled-atmosphere enclosure; and

when the blood bag has been removed from the controlled-atmosphere enclosure, one of *qualifying*, *requalifying*, or *dequalifying* the blood bag, wherein requalifying comprises determining when both the time dT and the expiration date have not expired, whereby the blood bag is returnable to the enclosure, and wherein dequalifying comprises determining that one of the time dT and the expiration date have expired, whereby the blood bag is to be destroyed.

As discussed above, LEVIN does not disclose defining a maximum allowed time dT for being kept outside a controlled-atmosphere enclosure. Additionally, as discussed above, LEVIN fails to disclose basing the status (requalified or dequalified), or the

above, LEVIN fails to disclose basing the status (requalified or dequalified), or the indication of that status, on the expiration of either or both of the maximum time dT and/or the expiration date. Moreover, for the reasons stated above, REBER does not compensate for the deficiencies of LEVIN noted above. Thus, Applicants submit that any proper combination of LEVIN and REBER would not teach all the features of at least claims 9, 19, and 26.

Dependent Claims 3, 7, 13, 15-18, 24-25, and 27-28

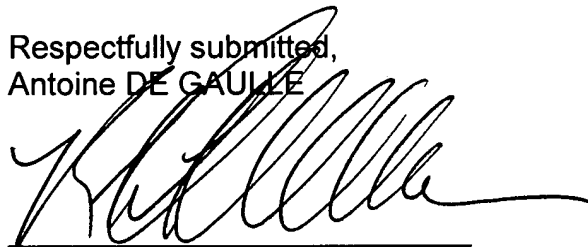
Claims 3, 7, 13, 15-18, 24-25, and 27-28 are dependent claims, depending from respective distinguishable base claims. Accordingly, these claims should also be in condition for allowance by virtue of their dependencies.

Accordingly, Applicant respectfully requests that the rejections over claims 1, 3, 7, 9, 13, 15-19, and 24-28 be withdrawn.

CONCLUSION

In view of the foregoing amendments and remarks, Applicants submit that all of the claims are patentably distinct from the prior art of record and are in condition for allowance. The Examiner is respectfully requested to pass the above application to issue. The Examiner is invited to contact the undersigned at the telephone number listed below, if needed. Applicants hereby make a written conditional petition for extension of time, if required. Please charge any deficiencies in fees and credit any overpayment of fees to Attorney's Deposit Account No. 19-0089.

Respectfully submitted,
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DRAWING REVISIONS

Attached hereto as an Appendix is a Replacement Sheet for Figure 1, without any markings. The changes to the drawings are explained below, in the "REMARKS" section. All of the drawings on the replacement sheet, as originally filed, are provided herein.